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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,932	11/03/2003	Michael Schink	104035.271139	4940

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
05/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/700,932	SCHINK ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-32,34-39 and 56-72* is/are pending in the application.

4a) Of the above claim(s) *30,35,58 and 60-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-29,31,32,34,36-39,56,57,59 and 67-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' election filed 03/03/2008; and response filed 01/10/2008 to the office action mailed 11/23/2007.

Claims 1-26, 33, 40-55 have been previously canceled.

Claims 27-32, 34-39, 56-72 are pending.

Response to Election/Restrictions

1. Applicant's election of species dexpanthenol and printing process in the reply filed on 03/03/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 35, 58, 60-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/03/2008.

Claim 30 has been previously withdrawn.

Claims 27-29, 31, 32, 34, 36-39, 56, 57, 59, 67-72 are included in the prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 28, 59 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" in claim 28 and the terms “portion” and “at least portion” in claims 59 and 69 are relative terms which render the claims indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification does define the degree of adhesiveness of the matrix retained and the original adhesiveness strength in order to set forth the metes and bounds of claim 28 by reciting “substantially”. The specification does not define amount of solvent evaporated and the amount retained to set forth the metes and bounds of claims 59 and 69. The term “at least portion” amounts to no evaporation and all the solvent is retained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 27, 28, 31, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 212 681 ('681).

EP '681 disclosed drug-releasing system comprised of a drug dispensing polyurethane matrix (abstract). The drug present in amount of 1-10% by weight of the matrix (co1.4, lines 50-51). The drug is dissolved in the matrix that further comprises permeation enhancer (col.5, lines 7-12). The polyurethane comprises hexamethylene diisocyanate and polyetherpolyol (col.7, lines 38-45). The adhesive characteristics of polyurethane as claimed by claims 27 and 28 are inherent. The reference does not disclose the polyurethane is foamed, therefore, the reference implied that the polyurethane is unfoamed.

Response to Arguments

7. Applicant's arguments filed 01/10/2008 have been fully considered but they are not persuasive. Applicants argue that the polyurethane disclosed by EP '681 is not self-adhesive because the reference disclosed additional adhesive layers on the polyurethane layer that is not optional. Applicants argue that the reference does not disclose the claimed polyurethane, and not all polyurethane are self-adhesives as it contains acrylyl chain terminator. Further, applicants argue that the reference does not disclose the active ingredients are applied to the preformed matrix or to a side thereof, but combined with the polyurethane matrix.

In response to these arguments, applicants' attention is drawn to the present claims that are directed to product, and all the elements of the product are disclosed by the reference. The incorporation of the active ingredients into the matrix as disclosed by the reference implies that some of the active ingredients are on the surface of the matrix. EP '681 teaches polyurethane absorbs water and dissolves the drug incorporated in the polyurethane (col.5, lines 40-46) leading to polyurethane matrix and dissolved drugs as instantly claimed. EP '681 disclosed polyurethane matrix made from polyetherpolyols and hexamethylene diisocyanate (second full paragraph of col. 7), therefore, the polyurethane disclosed by the reference is self-adhesive since compounds and their properties are inseparable. The claims' language does not exclude the presence of acrylyl chain. Furthermore, the additional adhesive layer disclosed by the reference is optional, implementing that the matrix itself is adhesive in absence of the skin contact adhesive. Even if the adhesive layer is not optional, the claims' language does not exclude the presence of other layers such as skin adhesive layer.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 27-29, 31, 36, 37, 68, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 6,191,216 ('216).

The teachings of EP '681 are discussed as set forth in this office action.

Although EP '681 disclosed polyurethane comprising hexamethylene diisocyanate and polyetherpolyol, however, the reference does not explicitly teach the specific polyetherpolyol as claimed by claim 29.

US '216 teaches polyurethane gel composition that is preferred to use in medical applications because it is strongly self-adhesive and it is suitable for sticking to the skin in wound dressing (col.4, lines 45-57). The self-adhesive polyurethane gels comprises polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of $\geq$ 10 wt. %, and hexamethylene diisocyanate (col.2, lines 3-13).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising polyurethane matrix comprising drug as disclosed by EP '681, and replace the polyurethane with the specific polyurethane gel disclosed by US '216 and comprising polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate, motivated by the teaching of US '216 that such a polyurethane gel composition is preferred to use in medical applications because it is strongly self-adhesive and suitable for sticking to the skin, with reasonable expectation of having drug releasing system comprising drug in polyurethane gel matrix comprising polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate that is strongly self-adhesive that sticks to the skin effectively.

Response to Arguments

11. Applicant's arguments filed 01/10/2008 have been fully considered but they are not persuasive. Applicants argue that EP '681 teaches oligomer cured by exposure to actinic radiation while polyurethane of US '216 is not an oligomer cured by actinic radiation, therefore there is no reason for one of ordinary skill in the art to employ polyurethane of US '216 instead of curable oligomer disclosed by EP '681.

In response to this argument, applicants' attention is directed to the scope of the present claims that is drawn to a product and all the element of the product are

disclosed by the EP '681, except to the specific physical properties of the constituents of polyurethane, and the method of making the polyurethane using actinic radiation disclosed by EP '681 is not excluded by the present claims, and do not distinguish the presently claimed product over the product of the prior art. EP '681 disclosed oligomer made from the reaction of diisocyanate with glycol (col. 4, lines 29-30 of EP '681). EP '681 teaches the generic constituents of the polyurethane, and US '216 teaches the species of the polyurethane that is made of polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate, and further teach such polyurethane is preferred to use in medical applications because it is strongly self-adhesive and suitable for sticking to the skin. Therefore, one having ordinary skill in the art would have been motivated to replace polyurethane disclosed by EP '681, whether cured by actinic exposure or not, whether oligomer or polymer, by polyurethane polymer disclosed by US '216 because US '216 teaches such a polyurethane as a preferred self adhesive to use in medical applications because it is strongly self-adhesive and suitable for sticking to the skin. US '216 is an analogous art, and is in the field of applicant's endeavor or, and reasonably pertinent to the particular problem with which the applicant was concerned, therefore, it is reasonable to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Furthermore, there is a reasonable expectation of success of obtaining drug releasing system comprising drug in polyurethane gel matrix comprising polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and

hexamethylene diisocyanate that is strongly self-adhesive that sticks to the skin effectively. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

12. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 by itself or in view of US '216, and further in view of US 6,399,092 ('092).

The teachings of EP '681 by itself or combined with US '216 are discussed as set forth in this office action.

However, the references do not teach that the polyurethane matrix comprises superabsorbent as claimed by claim 32.

US '092 teaches wound dressing superabsorbent polymer and active ingredient that when applied to the skin the superabsorbent absorbs fluid and slowly releases the active agent into the skin (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising drug in polyurethane matrix as disclosed by EP '681 by itself or combined with US '216, and further add superabsorbent to the drug containing matrix as disclosed by US '092, motivated by the teaching of US '092 that when superabsorbent is added to the drug containing matrix it absorbs fluid from the skin and slowly releases the active agent into the skin, with reasonable expectation of having drug releasing system comprising polyurethane matrix containing drug and superabsorbent that absorbs fluid from the skin and slowly releases the active agent into the skin, hence enhancing the drug release to the skin.

Response to Arguments

13. Applicant's arguments filed 01/10/2008 have been fully considered but they are not persuasive. Applicants argue that EP'681 requires water for the functioning of the delivery system. Accordingly, the presence of a superabsorbent in this system would be harmful in that the superabsorbent can be expected to absorb the water that is needed for dissolving the drug inside the matrix and for transporting it from inside the matrix to the skin. Accordingly, there is no reason for one of ordinary skill in the art to incorporate

a superabsorbent into the drug delivery system according to EP'681 and such a combination would not result in the subject matter of dependent claim 32.

In response to this argument, it is argued that EP '681 desired water absorption in order to release the active ingredients (col.5, lines 40-47), and US '092 teaches inclusion of superabsorbent polymer with the polymer composition forming wound dressing for slowly release of active ingredients (abstract; col.4, lines 31-38). Water absorption is desired by EP '681, and this would motivate one having ordinary skill in the art to look for superabsorbent disclosed by US '092 especially that US '092 teaches matrix comprising superabsorbent absorbs fluid from the skin and slowly releases the active agent into the skin, as desired by EP '681. US '092 is an analogous art, and is in the field of applicant's endeavor or, and reasonably pertinent to the particular problem with which the applicant was concerned, therefore, it is reasonable to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Furthermore, there is a reasonable expectation of having drug releasing system comprising polyurethane matrix containing drug and superabsorbent that absorbs fluid from the skin and slowly releases the active agent into the skin, hence enhancing the drug release to the skin. it has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When

the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

14. Claims 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 by itself or in view of US '216, and further in view of US 5,866,157 ('157).

The teachings of EP '681 by itself or combined with US '216 are discussed as set forth in this office action.

Although EP '681 teaches enhancer in the polyurethane matrix, however, EP '681 does not teach the specific enhancers disclosed by claim 38 or the thickness of the matrix as claimed by claim 39.

US '157 teaches patch formulation for delivering active agent to the skin that has increase percutaneous absorption of the drugs with extremely reduced skin irritation (abstract). The formulation comprises permeation enhancers including isopropyl myristate and menthol, which is an essential oil (col.5, lines 11, 14). The active

ingredients is present in an amount of 0.1-20% (abstract). The examples showed that the drug containing layer having thickness of 100 μm.

Therefore, US '157 showed that such thickness of the drug containing layer as claimed has been used in the art.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising polyurethane matrix comprising drug and permeation enhancer as disclosed by EP '681 by itself or combined with US 216, and replace the permeation enhancer with isopropyl myristate as disclosed by US '157, motivated by the teaching of US '157 that transdermal formulation comprising such enhancer has increase percutaneous absorption of the drugs with extremely reduced skin irritation, with reasonable expectation of having drug releasing system comprising polyurethane matrix comprising drug, isopropyl myristate that provides increased percutaneous absorption and extremely reduced skin irritation at the site of application.

15. Claims 34, 67 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 by itself or in combination with US '216, and further in view of US 6,630,442 ('442).

The teachings of EP '681 by itself or combined with US '216 are discussed as set forth in this office action.

However, the references do not specifically teach dexpanthenol as an active agent as claimed by claims 34, 67 and 72.

US ‘442 teaches composition comprises dexpanthenol that repairs and reduces skin damage because it is quick and deep penetrating moisturizer (abstract; col.23, lines 38-42).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polyurethane matrix drug comprising drug as disclosed by EP ‘681 by itself or combined with US ‘216, and use the polyurethane matrix to deliver dexpanthenol disclosed by US ‘442, motivated by the teaching US ‘442 that dexpanthenol repairs and reduces skin damage because it is quick and deep penetrating moisturizer, with reasonable expectation of having polyurethane matrix comprising drug and/or dexpanthenol that repairs and reduces skin damage effectively.

Response to Arguments

16. Applicant's arguments filed 01/10/2008 have been fully considered but they are not persuasive. Applicants argue that one having ordinary skill in the art would not e motivated to combine EP ‘681 with any of US ‘157 or US ‘442 because the references fail to cure the deficiency of EP ‘681 by disclosing matrix as claimed by claim 27 produced by applying active agent in liquid dissolved form to he side of already made polyurethane matrix.

In response to these arguments, and in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be

expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). US '157, US '442 or EP 032 are relied upon for the solely teaching that such active ingredients are suitable for topical or transdermal delivery. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

17. Claims 59 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '861 by itself or in combination with US '216 and further in view of US 6,183,770 ('770).

The teachings of EP '681 by itself or combined with US '216 are discussed as set forth in this office action.

Although EP '681 teaches drug is incorporation of the active ingredients into the matrix as disclosed by the reference implies that some of the active ingredients is on the surface of the matrix, however, the reference does not explicitly teach the application of the active ingredient on the surface of the adhesive, which step is directed to the method of making the device. Claims 59 and 69 recite "at least portion of the solvent remains in the matrix" and this interpreted as the amount of solvent remains may amount up to all the solvent.

US '770 teaches patch for delivering agents to the skin comprises a pad, having an upper and lower surface area, and an adhesive adhered on the lower surface area of the pad and an active agent for delivery to the skin is applied to the patch in a manner such that the deleterious effects of the adhesive on the active agent are minimized (col.1, line 63 till col.2, line 3).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch comprising polyurethane matrix incorporating drug as disclosed by EP '681 or EP '681 combined with US '216, and add active agent on the skin contacting surface of the polyurethane matrix instead of incorporating the drug into the matrix as disclosed by US '770, motivated by the teachings of US '770 that such a structure of the patch minimizes the deleterious effects of the adhesive on the active agent, with reasonable expectation of having transdermal patch comprising polyurethane matrix with drug/active agent is applied to the skin contact surface of the matrix wherein the deleterious effects of the adhesive on the active agent are successfully minimized.

Response to Arguments

18. Applicant's arguments filed 01/10/2008 have been fully considered but they are not persuasive. Applicants argue that US '770 does not teach evaporating the solvent so that none or at least portion of the solvent remains in the matrix.

In response to this argument, applicants' attention is directed to the scope of the present claims 59 and 69 that recite "at least portion of the solvent remains in the matrix" and this interpreted as the amount of solvent remains may amount up to all the solvent. In other words, the evaporation of solvent not required by the claims. In any events, applicants failed to show superior and unexpected results obtained from

evaporation of portion of the solvent, and such limitation does not impart patentability to the claims, especially the claims are directed to product.

19. Claims 56, 57 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 by itself or combined with US '216, and further in view of US 4,915,950 ('950).

The teachings of EP '681 by itself or combined with US '216 are discussed as set forth in this office action.

However, the references do not teach applying active ingredients by printing process as claimed by claims 56, 57 and 71.

US '950 teaches method of making transdermal drug delivery device wherein the method comprising applying the drug to the adhesive layer using printing technique because printing has the advantage of providing uniform deposition of the drug on the surface of the adhesive and eliminates the need for organic solvents and heat treatment (abstract; col.2, lines 47-56).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch comprising polyurethane matrix incorporating drug as disclosed by EP '681 or EP '681 combined with US '216, and apply the drug on the polyurethane matrix using printing technique as disclosed by US '950 because US '950 teaches that printing has the advantage of providing uniform deposition of the drug on the surface of the adhesive and eliminates the need for organic solvents and heat treatment, with reasonable expectation of having transdermal

patch comprising polyurethane matrix with the active agent uniformly provided on the polyurethane matrix using printing technique wherein the technique is safe and free from undesired effects of organic solvents and heat treatment and the active agent is distributed uniformly on the matrix.

Regarding specific printing processes claimed by claim 57, applicants failed to show superior and unexpected results obtained from such processes, therefore impart no patentability to the claim.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG